PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2002029-WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/DK2004/000011	International filing date *(day/month/year)* 12.01.2004	Priority date *(day/month/year)* 10.01.2003
International Patent Classification (IPC) or national classification and IPC A61F5/443, A61F5/448		
Applicant COLOPLAST A/S et Al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05.07.2004	24.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Neumann, E Telephone No. +31 70 340-3028

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000011

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-18	as originally filed
Claims, Numbers	
1-18	received on 07.03.2005 with letter of 07.03.2005
Drawings, Sheets	
1/3-3/3	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 14-16, 18

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 14-16, 18

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000011

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-13,17
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-13,17
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-13,17
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US 2003/004477 A1 (GOTHJAELPSEN LAILA BUSK ET AL) 2 January 2003 (2003-01-02)

D2: WO 98/53771 A (GOTHJAELPSEN LAILA BUSK ;CIOK DANUTA (DK); COLOPLAST AS (DK); SLET) 3 December 1998 (1998-12-03)

2.1 The document D2 is regarded as being the closest prior art to the subject-matter of claim 1 and shows (the references in parentheses applying to this document: see page 8, line 8 - page 9, line 5; figures):

An ostomy appliance body side member comprising, centrally, an adhesive wafer (2) having a first adhesive surface for securing the appliance to the user's skin and a second surface being covered with a carrier sheet (9), said wafer (2) having a hole for receiving a stoma *showing balanced plastic and elastic properties* (see item VIII point 1) wherein the part of the second surface of the wafer (2) surrounding the hole allows an adaptation of the size of the hole of the ostomy appliance to accommodate a stoma by enlarging the hole by rolling up the inner rim of the hole, to form a torus being locked in its rolled up position by the contact to the surface surrounding the stoma.

2.2 The subject-matter of claim 1 differs from this known document D2 in that

the part of the second surface surrounding the hole for receiving a stoma is provided with a hydrophobic adhesive compatible with the first adhesive surface of the adhesive wafer.

In view of said difference the subject-matter of claim 1 is new and meets the requirements of Article 33(2) PCT.

2.3 The problem to be solved by a hydrophobic adhesive is that it is more stable against the action of aggressive exudates, which will delay the deterioration of the adhesive wafer.
(see page 7, lines 13 - 20).

2.4 The prior art does not disclose a second surface provided with a hydrophobic adhesive in a rolled up position.

Therefore, the subject-matter of claim 1 involves an inventive step and meets the requirements of Article 33(3) PCT.
The ostomy appliance body side member described in claim 1 is industrially manufacturable and therefore also the requirements of Article 33(4) PCT are fulfilled.

2.5 Dependent claims 2 - 11 and 17 specify advantageous embodiments of the subject-matter of claim 1 and fulfill the requirements of Articles 33(2), (3) and (4) PCT as well.

3.1 The document D2 is regarded as being the closest prior art to the subject-matter of claim 12 and shows (the references in parentheses applying to this document: see page 8, line 8 - page 9, line 5; figures):

An ostomy sealing member (5) in the form of a mouldable mass or ring having a first adhesive surface which shows a sufficient adhesiveness to adhere to the skin and to seal around a stoma and between the stoma and an ostomy appliance adapted to receive secretions from the stoma, which sealing member (5) has a second surface facing away from the user, the second surface being covered with a top film (15), said sealing member (5) having a hole (3) for accommodating a stoma and said sealing member having *balanced plastic and elastic properties* (see item VIII point 1) allowing an enlargement of the hole (3) for receiving a stoma by rolling up the inner rim of the hole to form a torus before placing the sealing member around the stoma.

2.2 The subject-matter of claim 1 differs from this known document D2 in that

a part of the second surface surrounding the hole is provided with a hydrophobic adhesive which is compatible with the first adhesive surface.

In view of said difference the subject-matter of claim 12 is new and meets the requirements of Article 33(2) PCT.

3.3 The problem to be solved by a hydrophobic adhesive is that it is more stable against the action of aggressive exudates (see page 7, lines 13 - 20).

3.4 The prior art does not disclose a second surface provided with a hydrophobic adhesive in a rolled up position.

Therefore, the subject-matter of claim 12 involves an inventive step and meets the requirements of Article 33(3) PCT.

The ostomy sealing member described in claim 12 is industrially manufacturable and therefore also the requirements of Article 33(4) PCT are fulfilled.

3.5 Dependent claim 13 specifies advantageous embodiments of the subject-matter of claim 12 and fulfills the requirements of Articles 33(2), (3) and (4) PCT as well.

Re item VII

1. Independent claim 12 should have been cast in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

1. Independent claims 1 and 12 are not clear, contrary to Article 6 PCT for the following reasons:

The expressions "wherein the part of the adhesive waver surrounding the stoma shows balanced plastic and elastic properties" and "said sealing member having balanced plastic and elastic properties" do not reveal the extension of such "a part" and in what way the plastic and elastic properties are balanced. Page 13, paragraphs 2 and 3 describe the use of standard materials normally used for the preparation of such an ostomy body side member or ostomy appliance. It can be therefore assumed that by using standard materials the adhesive waver will show balanced plastic and elastic properties.

Claims

1. An ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the appliance to the users skin and a second surface being covered with a carrier sheet, said wafer having a hole for receiving a stoma and wherein the part of the adhesive wafer surrounding the stoma showing balanced plastic and elastic properties **characterized in that** the part of the second surface surrounding the hole for receiving a stoma is provided with a hydrophobic adhesive compatible with the first adhesive surface of the adhesive wafer allowing an adaptation of the size of the hole of the ostomy appliance to accommodate a stoma by enlarging the hole by rolling up the inner rim of the hole, to form a torus being locked in its rolled up position by the contact to the surface surrounding the stoma.

2. A body side member as claimed in claim 1 wherein the torus is locked to the second surface in its rolled position by the contact between the second surface and the first adhesive surface.

3. A body side member as claimed in claim 1, wherein the adhesive wafer is made from an adhesive comprising hydrocolloids.

4. A body side member as claimed in any of claims 1-3, wherein the carrier sheet is absent on a central part of the second surface surrounding the stoma.

5. A body side member according to claim 4 where the hydrophobic adhesive stretches under the edge of the carrier sheet.

6. A body side member as claimed in any of claims 1-5 wherein a release liner protects the second adhesive surface.

7. A body side member as claimed in any of claims 1-4, wherein the carrier sheet on a central part of the second surface of the adhesive wafer surrounding the stoma is provided with a weakening pattern defining a central part of the carrier sheet which may be detached separately.

8. A body side member as claimed in claim 7 wherein a detachable separator piece is located between the carrier sheet and the adhesive.

9. A body side member as claimed in any of claims 1-8, wherein the part of the adhesive wafer surrounding the stoma is in the form of an exchangeable sealing member disposed in a hole of the wafer and having a hole for accommodating a stoma.

10. A body side member as claimed in any of claims 1-9 , which is provided with coupling means for releasable attachment of a receiving bag.

11. A body side member as claimed in claim 10, wherein the coupling means are matching coupling rings.

12. An ostomy sealing member in the form of a mouldable mass or ring having a first adhesive surface which shows a sufficient adhesiveness to adhere to the skin and to seal around a stoma and between the stoma and an ostomy appliance adapted to receive secretions from the stoma, which sealing member has a second surface facing away from the user, optionally being covered by a top film, said sealing member having a hole for accommodating a stoma and said sealing member having balanced plastic and elastic properties allowing an enlargement of the hole for receiving a stoma by rolling up the inner rim of the hole to form a torus before placing the sealing member around the stoma and wherein a part of the second surface surrounding the hole is provided with a hydrophobic adhesive, which is compatible with the first adhesive surface

13. A sealing member as claimed in claim 12, wherein the sealing member is made from an adhesive comprising hydrocolloids.

14. A method of applying an ostomy appliance body side member as claimed in any of claim 1-11, comprising enlarging the hole by rolling up the inner rim of the hole, to form a torus being locked in its rolled up position by the contact to the surface surrounding the stoma.

15. A method of applying an ostomy appliance body side member as claimed in any of claim 2-11, comprising optionally removing the release liner, enlarging the hole by rolling the inner rim of the

hole adapting of the hole to the size of the stoma forming a torus, locking the torus to the second surface in its rolled position by contact between the second surface and the first adhesive surface, aligning the stoma and the hole of the ostomy appliance body side member for accommodating the stoma and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole.

16. A method of applying an ostomy appliance body side member as claim in claim 9 comprising a) locating the stoma and aligning the stoma and the hole of the body side member and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole, b) enlarging the hole of the sealing member by rolling the inner rim of the hole of the sealing member forming a torus, c) adapting the hole to the size of the stoma, d) locking the torus to the second surface of the sealing member in its rolled position by contact between the adhesive surface and the second surface of the sealing member, e) aligning the stoma and the second hole of the ostomy sealing member and f) placing the same in the first hole of the body side member on the abdomen of the ostomate with the stoma projecting into the second hole.

17. A body side member according to any of claims 1-9 wherein a receiving bag is secured to the carrier sheet on the second surface and the body side member and the bag is a one-piece ostomy appliance.

18. A method of applying a one-piece ostomy appliance according to claim 17 comprising enlarging the hole by rolling the inner rim of the hole adapting of the hole to the size of the stoma forming a torus, locking the torus to the first surface in its rolled position by contact between the second surface and the first adhesive surface, aligning the stoma and the hole of the ostomy appliance for accommodating the stoma and placing the ostomy appliance on the abdomen of the ostomate with the stoma projecting into the hole.